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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,163	04/14/2000	Igor Splawski	2323-150	8826

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,163

Applicant(s)

ABBOTT ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9,25-30 and 69-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,69,74 and 76 is/are allowed.
- 6) ☒ Claim(s) 5-7,9,25-30,70,71, 72,and 73 is/are rejected.
- 7) ☒ Claim(s) 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Non-Final Rejection

Claims 1, 5-7, 9, 25-30, 69-76 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/02 has been entered.

Applicants' traversal, the amendment to claims 1, 5, 7, 9, 25, 70-72 in paper no. 19 are acknowledged and considered.

Claim Objections

Claims 9 and 75 are objected to because of the following informalities: line 4 of claim 9 has the word "a". Remove the underline to overcome the objection.

The statement in claim 75, "**An** isolated nucleic acid" in claim 75 is improper format for a dependent claim." The dependent claim should state, "**The** isolated nucleic acid of claim 74, which is an RNA".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 7, 25-30, and 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "a polypeptide of SEQ ID NO: 2" in claim 7 is a relative term which renders the claim indefinite. The term "a polypeptide of SEQ ID NO: 2" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim does not define the metes and bounds of the term. There is only one polypeptide sequence for SEQ ID NO: 2. Suggest replacing the phrase with "the polypeptide of SEQ ID NO: 2".

Applicants' traversal is not applicable to the new rejection of claim 7 under 112 second paragraph.

Claim 25 recites the limitation "the DNA". There is insufficient antecedent basis for this limitation in the claim.

Applicant's arguments with respect to claim 25 have been considered but are moot in view of the new ground(s) of rejection.

Claims 27 and 29 recite the limitation "the isolated DNA". There is insufficient antecedent basis for this limitation in the claim.

Applicants' traversal is not applicable to the new rejection of claims 27 and 29 under 112 second paragraph.

Claims 26, 28, 30, and 70 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship is: how the mutated form is related to the pre-amble of the claim. The claim does not define the metes and bounds of the term "mutated form". Suggest amending the claim to read, "An isolated nucleic acid coding for a mutated form of the MiRP1 polypeptide sequence set forth in SEQ ID NO: 2, wherein said mutated form comprises SEQ ID NO: 2, except for an Ala at amino acid 81; a Glu at amino acid 9; a Thr at amino acid 54; or a Thr at amino acid 57".

Applicants' traversal is not applicable to the new rejection of claims 26, 28, 30, and 70 under 112 second paragraph.

Claim 71 is rejected under 112, second paragraph, for the phrase "An isolated nucleic acid **coding** for (a) a mutated form of the nucleotide sequence set forth in SEQ ID NO: 1 or (b) a nucleic acid. A nucleic acid codes for a polypeptide sequence and not a nucleotide sequence.

In addition, claim 71 recites the limitation "said nucleic acid" on line 2. There is insufficient antecedent basis for this limitation in the claim. The claim does not define which nucleic acid is being referred to by the limitation.

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Suggest amending the claim to read as follows: "An isolated nucleic acid **comprising** (a) a mutated form of the nucleotide sequence set forth in SEQ ID NO: 1 or (b) the full complement of **said mutated form**, wherein said mutated form comprises nucleotides 74-442 of SEQ ID NO: 1 **except for** a nucleotide change selected from the group consisting of: an A to a G at nucleotide 95; a C to a G at nucleotide 98; a T to a C at nucleotide 234; and a T to a C at nucleotide 243.

Applicants' traversal is not applicable to the new rejection of claim 71 under 112 second paragraph.

Claim 72 recites the limitations "the DNA of claim 70" or "said DNA". There is insufficient antecedent basis for this limitation in the claim.

Applicants' traversal is not applicable to the new rejection of claim 72 under 112 second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 6, 7, 9, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent No. 5,475,796). Brennan teaches a collection of non-identical nucleic acids capable of detecting polymorphisms. Specifically, Brennan teaches an array, which has every possible 10-mer attached to it (Example 3). One of these oligonucleotides would anticipate the

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probe or primer recited in the instantly rejected claims (Example 4, columns 9 and 10). Claims 5, 6, 7, 9, 72, 73 do not contain any structural limitation that defines the claimed probe or primer, except they hybridize to a nucleic acid encoding MiRP1 polypeptide set forth in SEQ ID NO: 2 or to a nucleic acid at a polymorphic site comprising SEQ ID NO: 2, wherein the polymorphic site is selected from the group consisting of nucleotide numbers 95, 98, 234, and 243. The nucleic acids taught by Brennan comprise at least a subset of non-identical nucleic acids would be capable of doing so by hybridization.

Applicant's arguments with respect to claims 5-7, 72, and 73 have been considered but are moot in view of the new ground(s) of rejection.

Claims 5, 6, 7, 9, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al. (US Patent No. 5,491,086). Gelfand teaches an oligonucleotide, SEQ ID NO: 12, which is 24 bases long and nucleotides 4-17 is 100% identical to nucleotide 87-100 of applicants' SEQ ID NO: 1 (column 25, lines 6-59).

Applicant's arguments with respect to claims 5-7 and 72 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 69, 74, and 76 are free of the prior art and are condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.

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The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priole
SCOTT D. PRIOLE, Ph.D.
PRIMARY EXAMINER